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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,518	04/25/2005	Thomas Dunker	Dunker, T. ET AL - 1 PCT	6031

25889 7590 03/17/2009

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EXAMINER	
STOUT, MICHAEL C	

ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
03/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,518	DUNKER ET AL.	
	Examiner	Art Unit	
	MICHAEL C. STOUT	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24th November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 April 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This detailed action is in regards to United States Patent Application 10/532518 filed 25 April 2005 and is a Final action. The amendments filed 11/24/2008 are being considered by the examiner. Claims 1-10 are currently pending. Claims 1, 4 and 10 have been amended.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, "a bending direction" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 1 recites "a bending direction" which lacks antecedent basis in the specification.

Claim Objections

Claim 1 objected to because of the following informalities: Claim 1 Lines 2 and 3 appears to comprise a typographical error and recites "for a biopsy cannula insertable into a proximal end of a biopsy cannula" and should be replaced with "for a biopsy cannula insertable into a proximal end of ***the*** biopsy cannula". Appropriate correction is required.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-4, 6, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgio (US 5,333,619) in view of Miller (US 6,416,484 B1).

Burio discloses a biopsy material holding device for a biopsy cannula insertable into a proximal end of a biopsy cannula and between an inner wall of the biopsy cannula and a tissue-removing cylinder to perform transcutaneous biopsies of tissues (best

shown in Figure 2), said biopsy material holding device comprising a wire (thin plate 3) having a proximal end, a distal end and a wire tip at said distal end (as best shown in Figure 1 the thin plate comprises a proximal end located at 2 and a distal free end having a tip). Burio fails to explicitly disclose the device with bevelling arranged at the wire tip, said wire beinq bent in a bendinq direction at a pre-stress angle arranged at the proximate end of the wire, said bevellinq facinq awav from the bendinq direction, so that causing the wire including the wire tip glides along the inner wall of the biopsy cannula when inserted into the biopsy cannula.

Miller teaches a biopsy holding device comprising a flexible distal section having a proximal and distal and a tip at said distal end with beveling arranged at the tip (cutting edge 81, see Figures 10 and 11 and Column 5, Lines 9-32), said distal section being bent in a bending direction at a pre-stress angle arranged at the proximate end of the distal section (Figure 10 shows the distal section being bent at an angle alpha in a bending direction),

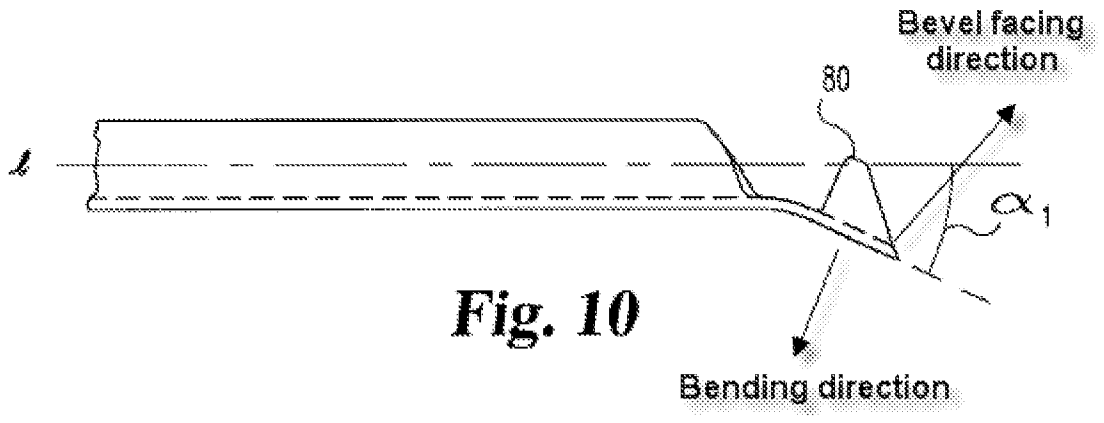

Fig. 10

said beveling facing away from the bending direction (see Figure 10 above), so that the wire including the wire tip glides along the inner wall of the biopsy cannula when

inserted into the biopsy cannula (the tip is capable of gliding along the inner surface of a cannula, see Column 4, Line 65 through Column 5, Line 8, see also Figure 9).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device taught by Burio to include a pre-streess angle as taught by Miller in order to further reduce damage to the core, see Column 5, Lines 1-8.

Regarding Claim 2, Burio in view of Miller teaches the biopsy material holding device for a biopsy cannula according to claim 1 further comprising a grip end, wherein said wire is attached to said grip end (Miller teaches the device comprising a grip, see Figures 16 or grasping lement cap 90, see Figure 7 and Column 5).

Regarding Claim 3, Burio in view of Miller teaches the biopsy material holding device for a biopsy cannula according to claim 1 further comprising a grip end with an attached extension shank, said wire being fastened to the shank (Miller as best shown in Figures 7 and 16 shows an extension shank (proximal portion of the cannula 74/71 having a handle attached at the proximal end) .

Regarding Claim 4, Burio in view of Miller teaches the biopsy material holding device for a biopsy cannula according to claim 1 wherein the wire tip has a bevelling angle B of 5° to 85° (as best seen in Figure 8 the beveling is arranged at an angle of between 5-85 degrees at about 45 degrees).

Regarding Claim 6, Burio in view of Miller teaches the biopsy material holding device for a biopsy cannula according to claim 2 wherein said wire is arranged at the

center of the grip end, with the pre- stress angle being between 1° and 90° (see Miller Column 4, Line 65 through Column 5, Line 8).

Regarding Claim 7, Burio in view of Miller teaches the biopsy material holding device for a biopsy cannula according to claim 1 wherein the wire has a length so that the wire reaches the distal end of the biopsy cannula when inserted in the biopsy cannula (see Miller Column 6, Lines 8-29, and Figures 9 and 13).

Regarding Claim 9, Burio in view of Miller teaches the biopsy material holding device for a biopsy cannula according to claim 3 wherein the wire is firmly connected to the distal end of the shank (best seen in Figures 7 and 8) and said pre-stress angle is between 1° and 90° (Column 5, Lines 1-8).

5. Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burio in view of Miller in further view of Janese et al. (US 4,781,202).

Regarding claim 8, Burio in view of Miller fails to disclose the device wherein the grip end can be locked into the proximal end of the biopsy cannula. Regarding Claim 8, Janese teaches a biopsy material holding device wherein the grip end can be locked into the proximal end of the biopsy cannula (Figure 1 shows the grip end (proximal end of the wire comprising the handle 10 inside the cannula hub 12 which locks the preventing it from movement perpendicular to the long axis of the cannula 26). Therefore it would have been obvious to a person of ordinary skill in the art at the time

of the invention to modify the device dislcosed by Burio/Miller as taught by Janese in order to prevent movement perpendicular of the tissue severing device and the cannula.

Regarding claim 10, Burio in view of Miller teaches the device wherein the wire ends at the direct end of the biopsy cannula after insertion of the shank and inserting the grip end into the proximal end of the biopsy cannula comprising lockable elements 51 etc and wherein the grip end is locable into the proximal end of the biopsy cannula. Burio in view of Miller fails to explicitly disclose the wire having a length of 25mm.

Janese teaches a biopsy material holding device wherein the grip end can be locked into the proximal end of the biopsy cannula (Figure 1 shows the grip end (proximal end of the wire comprising the handle 10 inside the cannula hub 12 which locks the preventing it from movement perpendicular to the long axis of the cannula 26) wherein the inner member ends at a direct end of the biopsy cannula when in the locked position, see Figure 10).

The matter of providing a wire with a length of 25mm is a obvious matter of design choice involving the change of size of a component, wherein no unexpected results are obtained over the prior art, the device would still perform the operation of taking tissue samples with reduced crush artifacts, see MPEP 2144.04. The obvious matter of a design choice is supported by Jenese which teaches a biopsy holding device comprising a wire having a bend section wherein the length of the angle to the tip is approximately 13mm and teaches that the size and length of the components can be varied depending on the application, see Column 4, Line 4-17 and Column 5, Lines 10-36). Thus it would have been obvious to a person of ordinary skill in the art to

modifty the device taught by Burio/Miller to include a lockable grip end and have a wire length of 25mm in order to prevent movement and provide a appropriately dimensioned device for a given application as taught by Jenese wherein the only difference is the relative size and has not different function from the prior art.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burio in view of Miller and in view of Fukuda et al. US Patent 6,322,581 B1.

Burio in view of Miller teaches the device wherein the tip comprises beveling, however Miller fails to explicitly disclose the tip comprising a hollow ground or bulged.

Fukuda teaches a various bevel finishes known in the art, for a suturing needle (wire) for medical use. Figures 4a thru 4e shows the bevelling on needles (wire) that are either hollow ground (52, Figure 4c) or bulged (51a, Figure 4b).

Because both Burio/Miller and Fukuda teach wires having beveled surfaces, it would have been obvious to one having ordinary skill in the art to substitute one type of bevelling for another to achieve the predictable result of creating the tissue biopsy holding device taught by Burio/Miller with the wire having a hollow ground or bulged bevel surface.

Regarding Claim 10, Burio in view of Miller teaches the biopsy material holding device for a biopsy cannula according to claim 3 wherein the qrip end is lockable into the proximal end of the biopsy cannula and the length of the wire is 25 mm and ends at

a direct end of the biopsy cannula after insertion of the shank and locking of the grip end into the proximal end of the biopsy cannula.

Response to Arguments

6. Applicant's arguments with respect to claims 1-10 are directed towards newly amended claim language and have been considered but are moot in view of the new ground(s) of rejection, presented in the above office action.

In regards to the applicants argument that the hinge portion of Miller is not a wire.

The Examiner disagrees. A wire given its broadest reasonable interpretation in light of the applicant's disclosure is a thin elongated piece of material.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736